

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-44. (Canceled)

45. (Currently amended) A composition comprising a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

- (a) between about 1% to about 15% of propofol;
- (b) between about 1% to about 4% of a propofol-soluble diluent selected from a medium chain triglyceride comprising medium chain fatty acids of synthetic or natural origin, or mixtures of said medium chain triglycerides;
- (c) between about 0.5% to about 5% of one or more surface stabilizing amphiphilic agents; and
- (d) from about 2.5% to about 20% of a pharmaceutically acceptable water-soluble polyhydroxy additive that acts as a tonicity modifier; and
- (e) water;

wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of ~~from about~~ greater than about 1.2 centipoise, and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

46. (Previously presented) The composition according to claim 45, wherein the surface stabilizing agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

47. (Previously presented) The composition according to claim 45, wherein the propofol-soluble diluent is selected from the group consisting of a synthetic fatty acid triglyceride, a natural fatty acid triglyceride, and mixtures thereof.

48. (Previously presented) The composition according to claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:3 to about 1:0.5.
49. (Previously presented) The composition according to claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:2 to about 1:1.
50. (Previously presented) The composition according to claim 45, wherein the propofol-soluble diluent is a mixture of medium-chain triglycerides and vegetable oil.
51. (Previously presented) The composition according to claim 50, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.
52. (Previously presented) The composition according to claim 45, wherein the composition contains about 2% to about 10% of propofol.
53. (Previously presented) The composition according to claim 45, wherein the pharmaceutically acceptable water-soluble polyhydroxy additive provides the propofol-containing dispersion or composition with an osmolality of about 250 to about 700 milliosmolal.
54. (Previously presented) The composition according to claim 53, wherein the osmolality is about 300 to about 500 milliosmolal.
55. (Previously presented) The composition according to claim 45, wherein the viscosity is from about 2 to about 5 centipoise.
- 56.-76. (Canceled)
77. (Previously presented) The composition according to claim 45, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.
78. (Previously presented) The composition according to claim 77, wherein propofol is present in an amount of about 2% by weight of the dispersion.
79. (Canceled)

80. (Previously presented) The composition according to claim 45, wherein the polyhydroxy additive is mannitol.
81. (Previously presented) The composition according to claim 80, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.
- 82.-86 (Canceled)
87. (Previously presented) The composition according to claim 45, wherein the medium-chain triglyceride is present in an amount of 4% by weight of the dispersion.
88. (Previously presented) The composition according to claim 45, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.
89. (Previously presented) The composition according to claim 45, wherein the amphiphilic agent is egg lecithin.
90. (Previously presented) The composition according to claim 89, wherein the egg lecithin is present in an amount of about 1% to about 7% by weight of the dispersion.
91. (Previously presented) The composition according to claim 90, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.
92. (Previously presented) The composition according to claim 91, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.
93. (Previously presented) The composition according to claim 89, wherein the egg lecithin contains not less than 98% phosphatidylcholine.
- 94.-95. (Canceled)
96. (Currently amended) The composition according to claim 45, wherein the amphiphilic agent is anionic dimyristoylphosphatidyl glycerol. ~~is present in an amount of 0.1% by weight of the dispersion.~~

97.-98. (Canceled)

99. (Currently amended) The composition according to claim 45, wherein the amphiphilic agent is selected from egg lecithin, which is present in an amount of 1.6% by weight of the dispersion, ~~and the anionic dimyristoylphosphatidyl glycerol, which~~ is present in an amount of 0.1% by weight of the dispersion, or a combination thereof.

100. (Previously presented) The composition according to claim 45, wherein the pH of the composition is about 4 to about 9.

101. (Previously presented) The composition according to claim 100, wherein the pH of the composition is about 5 to about 8.

102. (Previously presented) The composition according to claim 45, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

103. (Previously presented) The composition according to claim 45, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

104. (Previously presented) The composition according to claim 102, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

105. (Previously presented) The composition according to claim 45, wherein the dispersion is steam sterilizable.

106.-136. (Canceled)

137. (Previously presented) A composition of a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

- (a) propofol in an amount of about 2% by weight of the dispersion;
- (b) one or more medium-chain triglycerides in an amount of 4% by weight of the dispersion;
- (c) egg lecithin in an amount of 1.6% by weight of the dispersion;

- (d) anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion;
- (e) mannitol in an amount of 5.5% by weight of the dispersion; and
- (f) water.

138. (Canceled)

139. (Previously presented) The composition according to claim 137, wherein the medium chain triglyceride is of synthetic or natural origin.

140. (Previously presented) The composition according to claim 137, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

141. (Previously presented) The composition according to claim 137, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

142. (Previously presented) The composition according to claim 140, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

143. (Previously presented) The composition according to claim 137, wherein the dispersion is steam sterilizable.

144. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

- propofol in an amount of about 2% by weight of the dispersion;
- a medium-chain triglyceride in an amount of 4% by weight of the dispersion;
- egg lecithin in an amount of 1.6 % by weight of the dispersion;
- anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and
- mannitol in an amount of 5.5% by weight of the dispersion;

wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

145. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;

a mixture of medium-chain triglycerides in an amount of 4% by weight of the dispersion;

egg lecithin in an amount of 1.6 % by weight of the dispersion;

anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and

mannitol in an amount of 5.5% by weight of the dispersion;

wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

146. (Previously presented) The dispersion according to claim 144, wherein the medium chain triglyceride is of synthetic or natural origin.

147. (Previously presented) The dispersion according to claim 144, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

148. (Previously presented) The composition according to claim 144, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

149. (Previously presented) The dispersion according to claim 147, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

150. (Previously presented) The composition according to claim 144, wherein the dispersion is steam sterilizable.

151. (Currently amended) A composition comprising a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

- (a) propofol in an amount of from about 1% to about 15%;
- (b) a lipophilic propofol-soluble diluent in an amount of ~~up to~~ about 4% or less;
- (c) a surface stabilizing amphiphilic agent in an amount of between about 0.5% to about 5%;
- (d) a pharmaceutically acceptable, water-soluble, polyhydroxy additive that acts as a tonicity modifier in an amount of from about 2.5% to about 20%; and
- (e) water;

wherein the ratio of propofol to the diluent is about 1:4 to about 1:0.1 and the ratio of propofol to the amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of greater than about 1.2 centipoise; and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

152. (Currently amended) A composition comprising a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

- (a) propofol in an amount of from about 1% to about 2%;
- (b) a lipophilic propofol-soluble diluent in an amount of ~~up to~~ about 4% or less;
- (c) a surface stabilizing amphiphilic agent in an amount of between about 0.5% to about 5%;
- (d) a pharmaceutically acceptable, water-soluble, polyhydroxy additive that acts as a tonicity modifier, said polyhydroxy additive present in the dispersion in an amount of about 2.5% to about 20%; and
- (e) water;

wherein the ratio of propofol to the diluent is about 1:4 to about 1:0.1 and the ratio of propofol to the amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of greater than about 1.2 centipoise; and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

153.-155. (Canceled)

156. (Previously presented) The composition according to claim 151, wherein the water-soluble, polyhydroxy additive is selected from mannitol, trehalose, glycerol, sucrose, dextrose, lactose, or mixtures thereof.

157. (Previously presented) The composition according to claim 152, wherein the water-soluble, polyhydroxy additive is selected from mannitol, trehalose, glycerol, sucrose, dextrose, lactose, or mixtures thereof.

158.-159. (Canceled)

160. (Previously presented) The composition according to claim 45, wherein said composition prevents microbial growth, defined as no more than 0.5 log increase from the initial inoculum, of each of *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range 20-25°C, whereafter said aliquots are incubated at 20-25°C and are tested for viability of the microorganisms in the inoculated dispersion as determined by counting the colonies of said organism after 24, 48 hours and 7 days; and results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.

161. (New) The composition according to claim 151, wherein the propofol-soluble diluent is selected from the group consisting of saturated fatty acid esters, unsaturated fatty acid esters, esters of medium chain fatty acids of natural origin, esters of long chain fatty acids of natural origin, esters of medium chain fatty acids of synthetic origin, esters of long chain fatty acids of synthetic origin, triglycerides of medium chain fatty acids of natural origin, triglycerides of

medium chain fatty acids of synthetic origin, triglycerides of long chain fatty acids of natural origin, triglycerides of long chain fatty acids of synthetic origin and mixtures thereof.

162. (New) The composition according to claim 161, wherein the propofol-soluble diluent is a pharmaceutically acceptable vegetable oil, a pharmaceutically acceptable fish oil, or a mixture thereof.

163. (New) The composition according to claim 151, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of charged phospholipids of natural origin, uncharged phospholipids of natural origin, synthetic phospholipids, pharmaceutically acceptable non-ionic surfactants, cholesterol and combinations thereof.

164. (New) The composition according to claim 163, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of egg lecithin, soy lecithin, hydrogenated lecithin, phosphatidylcholines, phosphatidylglycerols, poloxamers, polaxamines, polyoxyethylene sorbitan esters and combinations thereof.

165. (New) The composition according to claim 152, wherein the propofol-soluble diluent is selected from the group consisting of saturated fatty acid esters, unsaturated fatty acid esters, esters of medium chain fatty acids of natural origin, esters of long chain fatty acids of natural origin, esters of medium chain fatty acids of synthetic origin, esters of long chain fatty acids of synthetic origin, triglycerides of medium chain fatty acids of natural origin, triglycerides of medium chain fatty acids of synthetic origin, triglycerides of long chain fatty acids of natural origin, triglycerides of long chain fatty acids of synthetic origin and mixtures thereof.

166. (New) The composition according to claim 165, wherein the propofol-soluble diluent is a pharmaceutically acceptable vegetable oil, a pharmaceutically acceptable fish oil, or a mixture thereof.

167. (New) The composition according to claim 152, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of charged phospholipids of natural origin, uncharged phospholipids of natural origin, synthetic phospholipids, pharmaceutically acceptable non-ionic surfactants, cholesterol and combinations thereof.

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168. (New) The composition according to claim 167, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of egg lecithin, soy lecithin, hydrogenated lecithin, phosphatidylcholines, phosphatidylglycerols, poloxamers, polaxamines, polyoxyethylene sorbitan esters and combinations thereof.